

**RULES
OF THE
TENNESSEE DEPARTMENT OF AGRICULTURE
DIVISION OF CONSUMER AND INDUSTRY SERVICES**

**CHAPTER 0080-04-13
FOOD MANUFACTURER, PROCESSOR, WAREHOUSE, AND DISTRIBUTOR REGULATIONS**

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0080-04-13-.01 APPLICABILITY.

- (1) This chapter applies to any person who operates in the state any factory, warehouse, establishment, or vehicle in which food is manufactured, processed, packed, held, or transported for introduction into commerce. However, these rules do not apply to any person whose operation is regulated under the Tennessee Egg Law, T.C.A. § 53-2-101 et seq., the Dairy Law of the State of Tennessee, T.C.A. § 53-3-101, et seq., or the Tennessee Meat and Poultry Inspection Act, T.C.A. § 53-7-201 et seq.
- (2) Persons licensed under this chapter shall be responsible for permitted facilities until: the applicable license expires, the department receives written notification from the licensee of a change in ownership for the licensed establishment, or the department receives written notification from the licensee desiring to terminate the license. The department shall not refund license fees for early termination of any license under this chapter.

Authority: T.C.A. §§ 4-3-203 and 53-1-207. **Administrative History:** Original rule filed December 23, 2015; effective March 22, 2016.

0080-04-13-.02 DEFINITIONS.

- (1) Terms in this chapter share those meanings of terms set forth in the Tennessee Food, Drug and Cosmetic Act, T.C.A. §53-1-101, et seq.
- (2) When used in this chapter, unless the context requires otherwise:
 - (a) Act means the Tennessee Food, Drug and Cosmetic Act, compiled at T.C.A. § 53-1-101, et seq.;
 - (b) Dietary supplement, food supplement, or words of similar import mean a product taken by mouth that contains a dietary ingredient; is intended to supplement the diet; and is not intended for use as a drug under the Act;
 - (c) Dietary ingredient means one or more of the following components when used in a dietary supplement: vitamins, minerals, herbs or other botanicals, amino acids, enzymes, tissues from organs or glands, concentrates, metabolites, constituents, or extracts;
 - (d) Food means those articles as defined under the Act and includes dietary supplements.

Authority: T.C.A. §§ 4-3-203 and 53-1-207. **Administrative History:** Original rule filed December 23, 2015; effective March 22, 2016.

0080-04-13-.03 LICENSE APPLICATION AND FEES.

- (1) All persons to whom these rules apply shall obtain a license in accordance with the Tennessee Food, Drug and Cosmetic Act and this chapter.
- (2) Application for issuance of any license under this chapter shall be made on forms provided by the department, which shall be completed in full and shall include:
 - (a) Name of the applicant;
 - (b) Proof of the applicant's registration in its state of incorporation, registration with the Tennessee Department of Revenue, or business license issued by a local governmental authority;
 - (c) Contact information for applicant, to include name of person legally responsible for applicant's operations, telephone number, email address, address of the principal place of business, and address of the facility to be licensed;
 - (d) Name and address of applicant's registered agent for service of process, if any.
- (3) Licensees shall notify the department in writing of any changes to the information or contents of an application within 30 days after the change takes place.
- (4) Applicants for licensure shall include with their application payment of an annual license fee as appropriate for the following categories of licenses. Fees designated under this rule shall be assessed in accordance with T.C.A. § 43-1-703(f) as it may be amended from time to time.
 - (a) Food Manufacturer License. A food manufacturer license is required for any factory or establishment in the state where food is manufactured, processed, or packed for introduction into commerce. Food manufacturer license fees are determined in accordance with the size of the manufacturer's facility and the degree of risk the manufacturer poses for outbreak of food borne illness. An establishment greater than 10,000 square feet must obtain a Large Facility license. An establishment equal to or smaller than 10,000 square feet must obtain a Small Facility license. Determination of a manufacturer's risk for outbreak of food borne illness is made by the department based on the nature of the manufacturer's operations. Fees applicable for a food manufacturer license are as follows:
 1. Food Manufacturer License, Large Facility – Risk Level 1: Tier 11 license fee;
 2. Food Manufacturer License, Small Facility – Risk Level 1: Tier 10 license fee;
 3. Food Manufacturer License, Large Facility – Risk Level 2: Tier 7 license fee;
 4. Food Manufacturer License, Small Facility – Risk Level 2: Tier 5 license fee;
 5. Food Manufacturer License, Large Facility – Risk Level 3: Tier 3 license fee;
 6. Food Manufacturer License, Small Facility – Risk Level 3: Tier 2 license fee.
 - (b) Food Warehouse License. A food warehouse license is required for any warehouse or establishment in the state where food is held for introduction into commerce. A food warehouse license is not required for any establishment licensed as a food

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manufacturer under this chapter or as a food establishment under R. 0080-04-09. Food warehouse license fees are determined in accordance with the degree of risk the warehouse poses for outbreak of food borne illness. This determination is made by the department based on the nature of the warehouse's operations. Fees applicable for a food warehouse license are as follows:

1. Food Warehouse License, Risk Level 1: Tier 11 license fee;
 2. Food Warehouse License, Risk Level 2: Tier 7 license fee;
 3. Food Warehouse License, Risk Level 3: Tier 3 license fee.
- (5) An applicant for licensure under this chapter shall remit its application and annual license fee to the department on or before July 1 of each year. All licenses issued under this chapter shall expire on June 30 following their issuance. If an applicant for renewal fails to remit payment of the license fee on or before July 15 of the licensure year for which renewal is sought, the applicant shall also be required to pay a late charge assessed under T.C.A. § 43-1-703 prior to renewal of the applicant's license.
- (6) The department may deny any application for licensure that is not completed in accordance with this rule.

Authority: T.C.A. §§ 4-3-203, 43-1-703, 53-1-207, and 53-1-208. **Administrative History:** Original rule filed December 23, 2015; effective March 22, 2016.

0080-04-13-.04 CERTIFICATES OF FREE SALE.

The fee for a Certificate of Free Sale is a Tier 2 fee under T.C.A. §43-1-703(f). No certificate of free sale shall be issued prior to receipt of the certificate fee.

Authority: T.C.A. §§ 4-3-203, 43-1-703, 53-1-207, and 53-1-208. **Administrative History:** Original rule filed December 23, 2015; effective March 22, 2016.

0080-04-13-.05 STANDARDS FOR MANUFACTURING AND PROCESSING.

- (1) Acidified Foods. The department adopts by reference, as if fully stated herein, the federal standards for acidified foods, compiled at 21 C.F.R. 108.25 and 21 C.F.R. 114, as either section or part may be amended from time to time.
- (2) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. The department adopts by reference, as if fully stated herein, the federal standards for good manufacturing, hazard analysis, and risk-based preventive controls, compiled at 21 C.F.R. 117, subparts A and B, as either subpart may be amended from time to time.
- (3) Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. The department adopts by reference, as if fully stated herein, the federal standards for good practice in manufacturing, packaging, labeling, or holding dietary supplements, compiled at 21 C.F.R. 111, as the part may be amended from time to time.
- (4) Fish and Fishery Products. The department adopts by reference, as if fully stated herein, the federal standards for fish and fishery products, compiled at 21 C.F.R. 123, subparts A and C, as either subpart may be amended from time to time.

(Rule 0080-04-13-.05, continued)

- (5) Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers. The department adopts by reference, as if fully stated herein, the federal standards for hermetically sealed low-acid foods, compiled at 21 C.F.R. 108.35 and 21 C.F.R. 113, as either section or part may be amended from time to time.

Authority: T.C.A. §§ 4-3-203 and 53-1-207. **Administrative History:** Original rule filed December 23, 2015; effective March 22, 2016.

0080-04-13-.06 STANDARDS FOR LABELING (RESERVED).

0080-04-13-.07 NOTICE OF ENFORCEMENT ACTION AGAINST LICENSEE.

Notice of an enforcement action against a licensee, including but not limited to assessment of a civil penalty and conduct of an administrative hearing, shall be presumed properly served upon mailing of notice to licensee's address of record with the department.

Authority: T.C.A. §§ 4-3-203 and 53-1-207. **Administrative History:** Original rule filed December 23, 2015; effective March 22, 2016.